Human embryo gene editing in China: the uncertain legal status of the embryo

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Human embryo gene editing in China: the uncertain legal status of the embryo [1]

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Abstract

In this article we examine processes of ethical deliberation, legislative developments, and social and political factors that have contributed to the emergence of human embryo gene editing as a field of life science research in China. For this purpose, we examine conceptions of the legal status of the human embryo in three domains of China's legal system: in patent law, in the jurisdictional domain of birth control, and in civil law. Each of these legal domains handles a different conception of the human embryo's moral and legal status, and in all three the embryo's status is contested and subject to changes. Our findings suggest that definitions of the legal status of the human embryo in China are at present in the midst of a renegotiation progress, which is driven by a variety of developments and causes. In this paper, we focus on three types of controversies that underlie this renegotiation process and we illustrate the conflicting aspirations, ethical arguments and moral priorities that inform these conflicts. We end this article with three lines of consideration that might structure future studies on this issue.

Keywords: CRISPR; human embryo gene editing; legal status of human embryo; research regulation; morality; China

Introduction

The genetic modification of human embryos is an ongoing and seemingly unstoppable development. Just days after a group of US researchers published a "warning" in the journal *Nature* on 12 March 2015, entitled "Don't edit the human germ line" (Lanphier 2015), Chinese scientists reported the first-ever experiment of gene editing in human embryos, in research linked to the blood disease beta-thalassemia (Liang et al. 2015). The team used the CRISPR/Cas9 system, a molecular technology that allows one to scan, splice and cut the genome of living cells and to "edit" (or re-write) it's DNA (Mans et al. 2015). Clustered regularly interspaced short palindromic repeats (CRISPR) technology is widely recognised as a "game changer" in life and health sciences because it allows fast, cheap and increasingly effective forms of genetic modification in living species, for a multiplicity of applications (Ledford 2015). Even though the Chinese researchers used tripronuclear zygotes (Liang et al. 2015),[2] which are unable to develop into a human being, the first report of human

[1] The first and second author equally contributed to this manuscript.

[2] Tripronuclear (3PN) zygotes result from fertilization of two sperms and one egg. Since tripronuclear zygotes lose the ability to reproduce as it contains 3 sets of chromosomes, Liang et al. (2015) argued that the use of these zygotes for research purposes is permissible from an ethical perspective.

embryo gene editing (HEGE) resulted in an outcry of public concern and fierce ethical debate (Bosley et al 2015). It is noteworthy, however, that the conclusions of the Chinese publication discouraged human gene editing in clinical applications by pointing to notable off-target effects, unwanted mutations and a low efficiency of homologous recombination directed repair (Liang et al. 2015). Based on these results, Xiaoxue Zhang, the managing editor of the journal *Protein and Cell* in which the article was published concluded, that any clinical use should be postponed until these problems are solved, and then proceed under strict regulatory oversight (Zhang 2015).

Despite these words of caution, many commentators fiercely criticized this study, with some claiming a clear ethical dividing line between China and "the West". According to *New York Times* reporter Didi K. Tatlow, for instance, "scientists in the west generally abjure this sort of research on the grounds that it amounts to genetic engineering of humans" (Tatlow 2015). Tetsuya Ishii, a bioethicist from Hokkaido University in Japan, argued in a similar vein. According to Ishii, China has a reputation for sometimes moving fast in the life and health sciences, and ignoring important ethical considerations in the process (Cyranoski 2015). A similar argument has been made by George Q. Daley, a stem cell scientist from Harvard Medical School, who suggested that lax jurisdictions might give rise to forms of experimentation regardless of the ethical and clinical problems (Vincent 2015). Most of these critics have claimed that the regulatory framework for human germ line editing is too liberal and insufficiently developed in China, and that as a result Chinese researchers are able to cross ethical boundaries that scientists in other scientifically advanced countries were not allowed to cross.

On the other hand, Chinese bioethicists and scientists have argued that there is no ethical or regulatory divide between China and Western countries in the human embryo gene-editing field. Zhai, Ng and Lie, for instance have suggested that many of the critical reactions among international commentators are based on misunderstandings and a "lack of willingness to acknowledge China as an equal partner in the international debate about proper limits to the development of new biotechnologies" (Zhai, Ng and Lie 2016). According to these authors, China has a well-developed regulatory framework for the governing of human germ line gene editing that is comparable to that of many developed countries. Regulatory instruments, as Zhai, Ng and Lie point out, include procedures for the management of human genetic resources issued by the National Health and Family Planning Commission (NHFPC), ethical principles for the governance of artificial reproductive technology (also by the NHFPC), good clinical practice standards from the China Food and Drug Administration (CFDA), and a regulation for the ethical review of biomedical research involving human subjects (Zhai, Ng and Lie 2016). These regulatory instruments require institutional review board (IRB) review for all forms of genetics research, and state that the collection, storage and use of human embryos, gametes and other genetic materials must "abide to the principles of autonomy and informed consent" (Zhai, Ng and Lie 2016). Most importantly, even though the use of embryo gene editing in basic and preclinical research is not prohibited in itself, the use of genetically modified gametes or embryos for clinical or reproductive purposes is explicitly banned (as laid down in the 2003 Technical Norms on Human Assisted Reproduction, issued by the NHFPC) (Zhai, Ng and Lie 2016).[3]

[3] It is relevant to point out in this regard that the Chinese Health and Family Planning Commission (which is the former Ministry of Health) and the China Food and Drug Administration have in 2009, 2012 and 2015 also introduced guidelines for stem cell therapies. In theory, these regulatory instruments also affect the clinical use of genetically modified embryos or gametes, at least a later

Conceptions of an ethical rift between China and other scientifically advanced countries are also contradicted by various recent developments. Permissions for the genetic editing of human embryos have in the meantime also been granted in the United Kingdom (Francis Crick Institute 2016), in Sweden (Callaway 2016) and the USA (Servick 2017). In contrast to the first study in China, which worked with embryos that were not viable for reproduction, the Swedish team uses completely healthy embryos that are able to develop to human offspring (Stein 2016). Moreover, calls for a global temporary moratorium on human germ line editing were rejected in an international summit on human gene editing that was coordinated by the US National Academy of the Sciences, in collaboration with the UK Royal Academy and the Chinese Academy of the Sciences in December 2015 (LaBarbera 2016). This meeting concluded that basic and preclinical research on human embryo and germ line gene editing should be allowed. The clinical use of human germ line editing, though, should be temporarily suspended until related safety and efficacy issues have been resolved (LaBarbera 2016).

In this paper, we set out to examine processes of ethical deliberation, legislative developments, and a variety of social and political factors that have contributed to the emergence of human embryo gene editing as a field of life science research in China. For this purpose we focus on three legal domains of China's legal system: patent law, the jurisdictional domain of birth control, and civil law. Each of these legal domains handles a different conception of the embryo's moral and legal status, and especially in civil law and patent law these definitions have been subject to contestation and ongoing transformation. In patent law, owing to the law's definition of the embryo's moral status, uses of human embryos for industrial or commercial purposes are excluded from patentability. This has resulted in the prohibition to patent human embryonic stem cells (hESC) and other inventions as well as biological derivates that include human embryos or gametes. In the legal domain of birth control, on the other hand, unborn human life has since the early 1980s gradually been de-humanized and been categorized as a form of (disposable) biological material, similar to blood or other human tissues. In civil law, finally, definitions of the legal status of human embryos are only gradually emerging. In China's first frozen embryo inheritance case in 2009, the embryo's legal status was defined as an "ethical object" (伦理物), which requires a higher level of moral respect than a common object, but which is not ascribed the same level of legal protection as a human being. These findings suggest that definitions of the legal status of the human embryo in China are at present in the midst of an ongoing renegotiation progress and subject to continuing changes. We will illustrate these debates and ongoing transformations in the empirical part of this paper, which follows the introduction. Then, in the discussion part of this paper we will reflect on the main factors that influence this negotiation process. We will show that at the heart of this dynamic is a clash between contrasting moral arguments and aspirations, which prioritize the realization of collective benefits for Chinese society, on the one hand, and the protection of the rights of individual citizens and the dignity of unborn human life, on the other.

Birth control and the legal status of the human embryo

Conflicts between the demands of science, historically evolved cultural values,

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point in time, provided clinical use of modified embryos will ever be approved. (See in this regard: Rosemann, Jiang and Zhang, accepted).

traditions and the particularities of different legal systems have resulted in controversies regarding the legal status of human embryos. This is well illustrated in China. As we will show, perhaps in part because of the challenges associated with regulating abortion, a critical awareness on the use and destruction of human embryos and foetuses for research purposes has emerged among regulators and the public. As we will illustrate in the subsequent sections, this is reflected in much of the commentary that addresses the legal status of human embryos in different legal domains in China. Let us first however take a historical view on perspectives of abortion in China, and how these have changed over time.

The late Qing government introduced the idea that abortion was defined as a criminal offense (Long 2012). However, before the enforcement of the Qing's criminal law, the Qing government dissolved in 1911. In the newly emerging Republic of China abortion was again criminalized. It was allowed only if the termination of a pregnancy was induced by a disease or life saving drugs (Long 2012). Unless the above applied, abortion was prohibited because the foetus was seen as being endowed with 'human right' (人权) and the right to live (生命). As the ethical scholar Guobing Song suggested in 1933, the foetus – from its starting point as a human embryo – has a right to live and is endowed with human rights. Since the foetus was defined as a human being, any abortion was considered equal to killing a person (Long 2012). Based on this, abortion was ethically identified as intentional killing.

Although the government of the Republic of China prohibited abortion and regulated abortion as criminal offense, abortion was still popular due to high demand.[4] Since abortion was recognized as a crime, doctors who were officially licensed were not willing to conduct abortion. Therefore, abortion was typically performed secretly in the Republican era. Most of the abortion cases that became known to the public were because women died as a result of the procedure (Long 2012). For these reasons, the number of abortion cases in that period seemed relatively low. In Fujian province, for example, the official number of abortion cases were only 26 from 1943 to 1947 (Long 2012). Hence, despite abortion constituting a criminal offense on paper, it was not strictly enforced. Abortion was not criminalized or persecuted in the same way as killing a person would have been.

After the foundation of the People's Republic of China (PRC), things gradually changed. Along with the country's growing population, abortion became an important part of public policy, closely bound to national interest. Family planning was first proposed in the report of 1st Five Year Plan (1953–57) (Pan 2006).[5] Then in 1972, the Chinese government introduced the "Later, Longer, Fewer" programme to reduce the average birth rate (Zhang 2006).[6] This campaign recommended smaller families by advocating a later age for marriage and birthing, and longer periods between births (Shen 1990). In order to increase controls on fertility levels, the government introduced in 1980 the "One-Child Policy", a fundamental national

[4] The reason for the big demand may lies in the lack of contraceptive measures at that time (Long 2012).

[5] The First Five Year Plan was drafted under the direction of the Central Committee of the Communist Party of China, and aimed to concentrate efforts on the construction of 694 large and medium-sized industrial projects to develop agricultural producers' cooperatives to help in the socialist transformation of the agriculture and handicraft industries and to put capitalist industry and commerce on the track of state capitalism (Pan 2006).

[6] "Later, longer, fewer" programme means later marriages, longer interval between births, fewer children. (See Zhang 2006).

policy that prescribed that one couple had one baby only (Shen 1990). Abortion became an important tool of population control and had the unique value in reducing birth rate (Wang 2006).[7] However, regarding abortion, there existed a fundamental difference between the two policies: while the "Later, Longer, Fewer" programme offered abortion services as a voluntary option, one-child-policy abortion became mandatorily enforceable by the state.

The historical overview above shows that the attitudes towards abortion were affected by the policies. The family planning policy required women who underwent forced sterilisation or abortion to devalue unborn human life. In Ankang city, of Shanxi province, a woman was forced late-stage abortion in 2012. The woman was given an injection to induce the abortion of her foetus in the seventh month. The family planning authority in Shanxi province said it was a serious violation of the regulations (Zhang and Sun 2013). The city government urged the county government to carry out an in-depth examination and suspended the director of the county's Family Planning Bureau.[8] However, many critics indicated that this and similar instances of late-stage abortion were not only related to the liability of administrative authorities, but also related to the cultural dehumanization of the human foetus (Zhou 2012).

Of interest, in the context of this article, is the fact that the one-child policy has not only affected couple's family planning decisions but also the legal status of unborn human life, including the embryo. From the perspective of the population policy, unborn human life that exceeded the permitted limits of the policy was no longer seen as being endowed with inherent human dignity.

Patent control and the legal status of the human embryo

With the development of biotechnology, the legal status of the human embryo started to be challenged and changed. Patent law is a good example to illustrate this point. The discovery of human embryonic stem cells, in particular, raised a series of ethical and public policy questions. For example, one of the most important patents in the stem cell field – the Wisconsin Alumni Research Foundation (WARF) patent application – reflected the interaction and tensions between morality and patentability in different world regions: the WARF invention was granted patent in the USA[9], but was rejected by the European Union (EU) because of a morality clause.[10] Under Article 53 of the European Patent Convention, patents shall not be granted to inventions that use human embryos for industrial or commercial purpose. The human body, at the various stages of its formation and development, and the discovery or isolation of its basic parts (such as stem cells), cannot constitute a patentable invention (Sterckx 2013).

Like the EU patent convention, the Patent Law of the People's Republic of China (Standing Committee 2008) contains a moral exclusion. As laid down in Article

[7] Professor Wang Jinying's research indicated that between 1972 and 2006 between 264 and 320 million births were prevented as a result of the birth control policy (Wang 2006).
[8] http://www.chinadaily.com.cn/china/2012-06/15/content_15503761.htm
[9] Primate Embryonic Stem Cell, U. S. Patent No.5, 843,780 (filed Jan.18 1996)(issued Dec.1 1998); Primate Embryonic Stem Cell, U. S. Patent No.6, 200,806 (filed Jan.26 998)(issued Mar 13 2001); Primate Embryonic Stem Cell, U. S. Patent No.7, 029,913 (filed Oct 18,2001)(issued Apr 18,2006)
[10] The application is involved with the destruction of human embryo, which is contrary to the article 53(a) – European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to interest public or morality, see G-02/06 of the Enlarged Board of Appeal of the European Patent Office.

5 of the 2010 Guidelines on the Examination of Patents, which was promulgated by Order Nr. 55 of the State Intellectual Property Office (SIPO 2010), the patent law states that "no patent right shall be granted for any invention–creation that is contrary to the laws of the State or social morality or that is detrimental to public interest" (SIPO 2010).[11] According to the explanation by the Commission of Legislative Affairs (CLA 2010), the 'social morality' standard depends on its acceptability by the public. If the invention is accepted by the public and by recognized moral standards, it may be granted a patent (CLA 2010) (Jiang 2016).

However, in practice it is not an easy task to determine whether a patent is publicly acceptable or not acceptable in China. First, due to the poor level of education (He 2016),[12] a large amount of people do not have the capability to fully understand the invention. Second, patents are still a relatively new system. For most people, patents represent advanced technology that could benefit human beings and as a result carry an 'odour of sanctity'.

In order to clarify the moral issues of human embryo patenting, the Guidelines for Patent Examination (that were launched by the State Intellectual Property Office of China) examined whether inventions involving human embryos are within the scope of Article 5 of patent law (*cf.* Jiang 2016). First, Article 3.1.2 in part II of chapter 1 in the Guidelines states that the use of human embryos for industrial or commercial purposes is contrary to social morality and therefore should be excluded from patenting (SIPO 2010). Second, Article 9.1.1.1 in Part II of chapter 10 of the Guideline states that "both an embryonic stem cell of human beings and a preparation method thereof shall not be granted the patent right in accordance with the provisions of Article 5" (SIPO 2010). Third, Article 9.1.1.2 in Part II of chapter 10 points out that "the human body, at the various stages of its formation and development, including a germ cell, an oosperm, an embryo and an entire human body shall not be granted the patent right in accordance with the provisions of Article 5.1" (SIPO 2010).

The above regulation shows that the moral standard in the patent law system is relatively high, which prevents the patenting of human embryos or hESC derived from human embryos for the reason that it involves destroying human embryos. In a patent application by Shanghai Genon Biological Product Co. Ltd. (Genon) 2 November 1999, referring to the preparation of pre-implantation embryos for therapeutic cloning use, the State Intellectual Property Office of China (SIPO 2013) rejected the application pursuant to Article 5 (Jiang 2016).[13] SIPO rejected the patent application for two reasons. The first was the fact that the preparation method of Genon was equivalent to human cloning, which falls within the moral exclusion of Article 5 (Wu 2013). The second was that the company targeted the use of human embryos for industrial and commercial purposes, which was a violation of Article 5 (Wu 2013). In 2004, Genon appealed to the Patent Review Committee (PRC) arguing that its invention would not violate Article 5 of the Patent law (Wu 2013).[14] The

[11] Part II of Chapter 1 of the Guidelines on the Examination of Patents by the State Intellectual Property Office of China further explained that "the connotation of the laws, administrative regulations, social morality and public interest is quite broad, which may vary with time and from region to region. Sometimes certain restrictions may be added or removed because of enactment and implementation of a new law or administrative regulation or amendment to or abolishment of a preceding law or administrative regulation. Therefore, the examiner shall pay special attention to this point in conducting examination according to Article 5" (SIPO 2010).

[12] According to the seventh national population investigation, 12445 out of every 100000 people had in 2016 an undergraduate degree (He 2016).

[13] This case was discussed in greater detail in: Jiang 2016.

[14] The argument includes first that, although the embryo includes human genetic information, it is an

committee re-examined the patent application and concluded that the invention was unlawful based on Article 5. The reason was that the patent claim does not exclude the possibility of the early embryos developing into humans. As the PRC argued, Genon had not provided sufficient evidence to prove that the embryos could not develop into human beings (Wu 2013).

Based on information from the search engine of the patent re-examination board of SIPO, a similar situation occurred in a patent application from the University of Pittsburgh in 2008 (the FS14444 re-examination decision)[15] and from Beijing University in 2010 (the FS24343 re-examination decision).[16] In these cases, although neither a legal definition of human embryos nor the scope of industrial or commercial use were provided, it is well established that under the Chinese Patent domain, any invention related to use human embryo for industrial or commercial use is prohibited from patenting as it destroys human embryos, which is contrary to the morality based on Article 5 of patent law (Jiang 2016).[17] That the human embryo shares the legal status of human beings is the reason why destroying human embryos is contrary to morality

Civil Law: The first frozen embryo inheritance case – the embryo as an ethical object

While within the Chinese Patent domain the human embryo is conferred the legal status of human being, this perspective creates problems with the reality of fertility clinics. Reproductive centres and in-vitro fertilization (IVF) clinics have to deal with large numbers of human embryos that are left over by IVF. Since the birth of the first IVF baby in 1978, IVF has been widely practiced. Millions of IVF cycles have resulted in a large number of frozen surplus embryos, which are no longer of use to couples (who either got a child or gave up IVF treatment) (Tu 2008; Wahlberg 2016). It is a big burden for hospitals to maintain these embryos. Many hospitals are facing the dilemma of whether to keep or discard frozen embryos that are left over by IVF. Some hospitals choose to destroy them. For example, Jiangsu Province's People's Hospital announced it intends to dispose of nearly 10,000 frozen embryos from untraced parents (Beijing Times 2015).

In 2014, a case concerning the inheritance of frozen embryos sparked off widespread debate regarding the legal status of frozen embryos (Zhang, Fan and Zhuang 2014). The case referred to an application by two elders, Mr. Shen and his wife. They filed a suit to claim the inheritance of four embryos left by their son in November 2013. The context of this case is that Mr. Shen's son and daughter-in-law used IVF at an infertility hospital in Nanjing. However, the young couple died in a car

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human-animal hybrid, not a human embryo. Thus, the invention is not related to the industrial or commercial use of a human embryo. Second, the embryo created by this method has no possibility of becoming human because claims 1-10 of the application contain no human-cloning steps. Third, the invention represents one aspect of human organ transplantation technology. Therefore, the invention is properly classified as therapeutic cloning. Neither its aim nor its method involves human cloning. In conclusion, the invention is not against the law, social morality or the public interest. (Wu 2013).

[15] See the FS14444 re-examination decision by the patent review committee. (In Chinese). http://app.sipo-reexam.gov.cn/reexam_out1110/searchdoc/decidedetail.jsp?jdh=FS14444&lx=fs, accessed 23 January 2017.

[16] See the FS24343 re-examination decision by the patent review committee. (In Chinese). http://app.sipo-reexam.gov.cn/reexam_out1110/searchdoc/decidedetail.jsp?jdh=FS24343&lx=fs, accessed 23 January 2017.

[17] This case was discussed in greater detail in: Jiang 2016

accident before implantation. The husband and wife were both the only child in their respective families. Four embryos from the young couple were created in the infertility clinic, and were frozen in liquid nitrogen at the time of the couple's death. The parents of both children wanted to inherit these embryos. As a mutually agreeable compromise could not be found between the two families, Mr. Shen and his wife chose to sue their in-laws (Zhang, Fan and Zhuang 2014). Interestingly, this case revealed that the current Chinese legal framework left a vacuum regarding the legal status of the human embryo. Frozen embryos were treated through the legal category of an "ethical object" (伦理物) instead of a "human being". The ethical object is different from a common object in civil law. While an "ethical object" requires a certain level of consideration and protection in civil law, the application of this category to the human embryo was unprecedented. This resulted in a legal conflict and different rulings of the lower and higher court in Jiangsu province. In May 2014, the Yi Xing court in the Chinese province of Jiangsu ruled that the frozen embryos could not be inherited by the dead couple's parents. For one thing, the hospital which had provided the IVF treatment (and which was later added as a third party by the judge in this case) declined to hand over the frozen embryo to either party in the dispute. For another thing, the court held that frozen embryos created by IVF have the potential to develop into a human being, which should be identified as a special thing (ibid.). Therefore, in their capacity as "ethical objects" these frozen embryos cannot be transferred or inherited as property. The frozen embryo, from the viewpoint of the court, can only be used for reproductive purposes by its biological originators. Since the young couple had died and surrogate birth is illegal in China, the reproductive purpose of the four frozen embryos can no longer fulfilled (ibid.).

Mr. Shen and his wife appealed to the higher court. The intermediate People's Court of Wuxi City dismissed the verdict of the lower court and ruled, in September 2014, that the four frozen embryos could be taken under the custody of the dead couple's parents. The court concluded that no regulation governed the question of the moral status of the human embryo. Hence, the court held that three important factors should be weighed in respect of the ownership of frozen embryos (Shi, Zhang and Zhuang 2014). First, the frozen embryo from IVF contains the unique genetic information of the young couple's families. The parents of the young couple are intensely connected to the frozen embryos by consanguinity. Second, the death of the young couple was a huge blow to their families and the four embryos became a source of hope for the continuation of their children's life and comfort. Indeed, the potential of frozen embryos could heal the parents from the pain of losing their children. Third, like the lower court, the appeal court held that the frozen embryo is recognized as an "ethical object", which requires a higher level of moral respect than property. The frozen embryos should be valued and protected by people who have the closest relationship with them. Since the young couple died in a car accident, their parents should be allowed to arrange for the fate of those embryos (ibid.). Respectfully, based on the above analysis, the intermediate People's Court of Wuxi City finally ruled that the parents of the young couple could inherit the four frozen embryos.

It is noteworthy that both the lower court and the higher court recognized the frozen embryo as an "ethical object", which is different from the legal categories "special thing" or "mere material property" as it has the potential to develop into a human being (Yang 2014).[18] However, the lower court ruled that the "ethical object",

[18] This distinction of the court was based on the work of the legal scholar Yang Lixin, who divided things into three groups: (1) the ethical thing, (2) the special thing and (3) property, in which the ethical

in the case of a frozen embryo, cannot be transferred or inherited, while the higher court ruled that it could be inherited (Sun 2015). Despite the fact that the two courts recognized the frozen embryos as "ethical objects", the ownership and transferability of human embryos between family members has not been clarified in law. This is reflected by the fact that the embryos could either be inherited or not be inherited depending on a different court's decision. From this perspective, the recognition of human embryos as "ethical objects" seems meaningless and insufficient. To make matters worse, no specific ethical rules have yet been provided for the legal category "ethical object".

Nevertheless, the court case related to the inheritance of the four frozen embryos case had public repercussions. The China Central Television broadcasted this case in several programs. The case was also selected as one of the ten biggest civil cases in China in 2014. Some commented the decision indicated the success of ethics and family relationship (Yang 2015). The intermediate court determined that the human embryo is to be classified as "an ethical object" which deserves special protection. But the court provided no direct reference to whether these frozen human embryos were to be seen as human beings or as property. As an alternative, the court used the principle of "ethical care" and "family relationship" to rule that frozen embryos could be inherited by the family. The court contended that to let the family rather than the state deal with the frozen embryos is in the best interest of the frozen embryos, since close family members have a more intimate relationship with them. The decision shows, to some extent, that the legal system in China is increasingly paying attention to humanistic care.

Discussion

These findings suggest that definitions of the legal status of the human embryo in China are at present in the midst of a renegotiation process and subject to changes. The different legal domains discussed in this paper do not only create ambiguity over the embryo as a legal and moral object, but they also create a problem space for embryos that allows their status to be discussed and redefined. In these different domains and in relation to different types of technologies (IVF, embryo freezing, stem cell research and abortion) the embryo emerges as a sort of layered boundary object. These multi-layered conceptions are influenced and changed furthermore by the recent softening of the one-child policy and other cultural and political changes.

In which ways are the divergent notions of the embryo influenced by wider socio-political factors and China's ambition to establish itself as a leading global player in science and technology research? As Sheila Jasanoff observed, different societies take on different ethical and legal models when taking decisions involving science and technology (Jasanoff 2005). The rise of a biopolitical sphere and life science economy in China offers unique insights about the change of the legal status of human embryos (Adams et al 2010). The uncertain legal status of the human embryo serves the rapidly changing politics of China: from the Maoist revolution to the current efforts to build a socialist political economy. The uncertain legal status of the human embryo serves the specific aims and relationships that maintain the social and political ambitions of these changing politics in China (Thomson 2010).

We suggest that the ongoing changes of the embryo's legal and moral status

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thing is worth of the highest moral standard (Yang 2014).

are shaped by various developments and causes. A first, more general, point is that new technological uses of human embryos, foetuses or gametes (in the context of novel types of research and technology applications) create specific sets of moral, social, legal and political challenges. The surfacing of CRISPR-based embryo gene editing, for instance, has given rise to different questions and dilemmas than those related to human embryonic stem cell (hESC) research or, previously, the invention of human reproductive IVF. Each of these technologies has necessitated a reconsideration of the ontological, moral and social status of embryos, which in turn has influenced legal and regulatory debates on the embryo's status.

Another element is the existence of a political and social climate in China that has emphasized rapid economic growth and scientific progress for many years. There are three push factors in particular which have propelled research with human embryos and other reproductive tissues in the last fifteen years or so in China: (i) the prospect of new economic opportunities and profits; (ii) the promise of medical progress; and (iii) the realization of new techno-scientific advances. As a rapidly developing country that aims to solve its internal social problems and to successfully compete with high-income countries, China has often pursued a more "pragmatic" and at times "aggressive" development model. The existence of too many safeguards and too much regulation has often been seen as "suffocating" economic and techno-scientific progress rather than promoting it, although the risks for China's citizens have at times increased as a result (Bound et al, 2013). Human embryo genome editing, and previously hESC research, promises significant advances in all three of these areas. This is why investment and research in these fields have been strongly endorsed by many in China and many other countries. These push factors have a strongly legitimizing effect on research with human embryos, and they play an important role in shaping the debates through which legal conceptions of human embryos are defined and revised. In the case of human embryo and germ line gene editing, we still see another at present less influential push factor: discourses that stress potential advantages of human enhancement (beyond purely medical interventions). Although highly controversial and still far off in technical terms, the genetic modification of human beings for enhancement purposes is associated by many with benefits. Proponents for genetic modification of humans beyond the medical realm can be found in both Western countries and China (Savulescu et al 2015).

Of interest, in this regard, is the fact that each of these three factors is associated with very specific conceptions of social benefits. Like in many other countries, for the government and stakeholders in China, biotechnology is not merely about economic profits, but related to national security and the management of a risky future, such as food security and environmental preservation (Ong 2010). Moreover, the realization of these benefits is often portrayed as a compelling moral imperative. The opening up of new economic possibilities, profits and sectors is seen as a key driver for long-term economic development in China, which in turn is a precondition to guarantee social stability, employment and the well-being of citizens. Medical progress, on the other hand, promises new treatments and better health care. It also improves the health of China's population at a higher level. Advances in hESC, pre-implantation genetic diagnosis (PGD), and now human genome editing, give new hope for the cure (or prevention) of previously incurable diseases. This involves also the reduction of births resulting in serious disabilities or birth defects, which continues to be an important goal in China's population politics. The realization of new techno-scientific breakthroughs, in turn, lies at the core of realizing the transition

of China from a production-based model of economic development to an innovation society. As China's 13th Five Year Plan (2016–20) has once again clarified, the aim is to compete globally at the cutting edge of science and technology research. Investments in stem cell and genetics research have been announced as key investment areas (Cyranoski 2015). CRISPR research has especially been encouraged by the Chinese Government. Fifty-seven programmes involving CRISPR research had, by October 2016, been approved and funded by the National Natural Science Foundation of China. The total funding of these programmes is more than 31 million RMB (Biological Discovery Network 2015). But investments into human gene editing research, including CRISPR-based research with human embryos, have also been made by the private sector. Professor Junjiu Huang, the principal investigator of the first-ever published human embryo gene editing article, reportedly received three million RMB of research funds from a private company called JinJia Group (Yang 2015).

Another factor that has influenced discourses and debates on the legal status of the human embryo is China's population politics. More than three decades of the one-child policy (which in 2015 was transformed to a two-child policy) have had an effect on attitudes towards abortion. While the moral imperative of the policy was to promote the well-being of China's huge population as a whole (by protecting the country from over-population and potentially chaos, famine and social unrest), 35 years of population control have left a mark: the policy defined embryos and foetuses as removable entities that could be aborted, discarded or used for research without much moral scruples or consideration (Greenhalgh and Winkler 2007); regardless of the views of the women, couples and families that were affected by the policy (Nie 2005). In legal terms, the continuity of unborn babies of families who already have one child (since January 1 2012, two children) was transferred from the parents to the state, which has the right to insist on pregnancy termination and to execute sanctions if people resist the policy.

It is difficult to say, though, exactly in which ways the socio-cultural impact of the one-child policy has influenced debates on the legal status of human embryos. One has to be extremely careful not to overestimate the impact of China's population politics or to misinterpret conceptions of the low status of unborn human life in the context of the population policy as being representative for the perceptions of Chinese citizens and scientists at a general level. As various studies have shown, assumptions that human embryos and foetuses are generally seen as being of low value in Chinese society due to the high numbers of abortions in the context of the population policy (Mann 2003; Cookson 2005) have proven wrong (Rosemann and Luo, under review). Research among Chinese IVF patients, students and women's groups, for example, has shown that the perceptions and ascribed value of human embryos are diversified and complex in China and that for many people the donation of human embryos for research or commercial purposes is unthinkable (Jin et al. 2013; Rosemann and Luo, under review). This body of research has illustrated that human embryos and foetuses in China are embedded in a complex and at times conflicting web of cultural meanings, values, emotions and social relations. As numerous commentators have pointed out, these perceptions often stand in stark contrast with conceptions of the "low status" of unborn human life in the context of the one-child policy (Sleeboom-Faulkner 2014; Hu 2009; Rosemann and Luo, under review). This line of research has also illustrated that many of the conceptions and values through which IVF patients make sense of their embryos or eggs are grounded in cultural traditions, folk beliefs and the social norms of rural culture. They often represent a highly prudent and

conservative view on the transfer or sale of human embryos (and other human tissues such as blood or organs) to others and to their use in research (Jin et al 2013; Rosemann and Luo, under review). As our empirical data suggest, these culturally mediated conceptions of morality and social norms also play a role in the ongoing renegotiation process regarding the embryo's legal status.

Three lines of controversy that underlie the re-negotiation of the embryo's legal status

Our findings suggest that the current renegotiation of the legal status of unborn human life in divergent domains of China's legal system reveals a set of controversies and contradictions that unfold along three dimensions. The first of these is a conflict between conceptions of morality that prioritize the realization of collective benefits and interests versus the protection of individual interests and rights. As Aihwa Ong highlighted the complex ethical dilemmas of the life sciences in China, Singapore, South Korea and other Asia countries, biotechnology seem to be a necessary tool for defining and solving problems of collective interests (Ong 2010). As China shifts from a manufacture-based economy to a knowledge-based economy, biotechnology refers to the fate of the wider community and national power. Biotechnology is no longer a purely technical context, but is closely enmeshed with cultural beliefs and conceptions of a common future. Conceptions of collective morality are embedded in the aforementioned push factors of long-term economic development, improved health, scientific advances and the prevention of over-population. Each of these goals is related to social stability and the well-being of China's society as a whole. This collective orientation conflicts, however, with the protection of the interests and rights of individual citizens (and human embryos and foetuses themselves). While this clash is most apparent in the context of the population policy, in patent law and civil law the protection of individual interests is increasingly acknowledged. Both, the biological originators and human embryos themselves are seen as requiring special protection, and are granted rights that prevent commodification or unwanted destruction. The protection of individual citizens (especially IVF patients) is also reflected in the artificial reproduction technology (ART) law and the regulation of hESC research. These are based on the bioethical principles of autonomy, informed consent, the right to refuse embryo (or gamete) donation, and the recognition of IVF patients as the legal owner of human embryos and gametes (Cheng et al. 2006).

A second dimension that has influenced the re-articulation of the embryo's legal status is a clash between the striving to establish China as a modern innovation society and global economic powerhouse and attempts to shape the acceptable limits of this process. This is most clearly reflected in the discourse surrounding the prohibition to commodify and patent human embryos and corresponding derivates (such as hESC or genetically modified embryos or germ cells). As the 2010 Guidelines for Patent Examination state in its moral exclusion clause, "no patent right shall be granted for any invention–creation that is contrary to … social morality or that is detrimental to public interest" (SIPO 2010). It is clear that from a purely economic perspective the patenting of hESC or other reproductive tissues can be beneficial. In the USA, for instance, the patenting of hESC and other human tissues is permitted and seen as a prerequisite to secure profits in this research field (Matthews and Cuchiara 2014). According to the Chinese patent system, however, the use of the 'human body at various stages of its formation and development, including [as] a germ cell, an embryo and an entire human body' for industrial and commercial

purposes is seen as contrary to social morality and has, as a result, been excluded from patenting (SIPO 2010; Article 9.1.1). This decision is part of a wider critical discourse that problematizes the commodification of human tissues and body parts in China, and sees it as detrimental to public interests and socialist modernization (SIPO 2010; Article 3.1.2).

A third area of contention, which is closely related to the previous one, is a clash between more "traditional" values and social norms, and the "modernist" ethos of techno-scientific progress that plays an important role in China. This is well illustrated in the moral discourse surrounding the use of human embryos for hESC research. A "modernist" ethos is represented in most of the scientific, policy and even bioethical discourse on the issue. While it is widely acknowledged that the human embryo (and the donors of human embryos) require special protection, its use for research purposes is legitimized because hESCs 'have the potential to cure millions of patients' (Qiu 2007). In this order of discourse, moral and ontological conceptions of the embryo usually classify it as a "de-personalized" and "unspiritual" form of biological matter, which is full of promissory value but devoid of religious, cultural or social meanings and value (Yang 2003; Cong 2008). This often stands in contrast, however, with the viewpoints and perceptions of ordinary citizens in China. As mentioned above, various empirical studies have shown that among IVF patients the use and destruction of embryos for research are often highly contested (Jin et al. 2013; Rosemann and Luo, under review). Reasons that have been cited are (i) that IVF couples see their surplus embryos as potential children which are part of the family and ancestral line, (ii) emotional attachment to these embryos and corresponding moral conflicts, (iii) resistance to embryo donation due to religious concerns, (iv) the rejection of the idea that donated embryos shall be used for the generation of profits, and (v) the existence of "feudal thoughts" and "folk beliefs" that prohibit the donation of body parts to anyone outside the family and blood line (Hu 2009; Mitzkat, Haimes and Rehmann Sutter 2010; Jin et al. 2013; Sleeboom-Faulkner 2014; Rosemann and Luo, under review). In current debates on the legal status of the embryo, these moral concerns are now gradually acknowledged in China. They are reflected, for instance, in the morality clause of patent law, and in the decision that the patenting and commodification of human reproductive (and other human) tissues is contrary to conceptions of public morality and social order. The subjective value of embryos are also reflected in the above-mentioned civil law case, where the emotional significance of the inherited frozen IVF embryos for the grandparents has been acknowledged, and used as the basis to reverse the decision of the lower court. However, because public debate and deliberation on the use of human embryos for hESC and more recently human gamete and embryo gene editing have so far occurred on a small scale in China, the viewpoints of citizens have often been under-represented or been absent in debates on the legal status of embryos.

Conclusion

In this paper we set out to examine processes of ethical deliberation, legislative developments, and a variety of social and political factors that have contributed to the emergence of human embryo gene editing as a field of life science research in China. For this purpose we have conducted an analysis of legislative developments in three domains of China's legal system: patent law, the jurisdictional domain of birth control, and civil law. As we have shown, in each of these domains the legal status of human embryos is defined differently. Moreover, definitions of the legal status of embryos

are subject to ongoing contestation and changes in patent and civil law. To explain these changes, we have examined a variety of social and political factors that have influenced legal debates on the embryo in China. We have suggested that the dilemmas that result from the emergence of new ways of using human embryos in research, together with the existence of conflicting social aspirations and moral values, have resulted in a continuing renegotiation process of the embryo's legal status in China. As we have illustrated, this process is driven in particular by three areas of contention. First, contrasting conceptions of morality prioritize the achievement of collective benefits (at the level of China's society at a larger level) and the protection of individual rights and interests (at the level of both embryo donors and the moral status of human embryos themselves). A second area of contention that has influenced legal definitions of embryos, in particular in patent law, is a conflict between the move toward rapid economic and technology modernization and initiatives to shape acceptable limits of this process. This has been expressed most clearly in the prohibition of the capitalization of human reproductive tissues and body parts, which is seen as detrimental to public morality and order. A third and closely related point is a clash between values and social norms that are grounded in China's cultural "traditions" and the more "modernist" ethos of radical scientific progress.

As we have documented, conceptions of the human embryo as a "de-personalized" and "unspiritual" biological entity in policy and law do frequently conflict with the perceptions of individual citizens, who perceive human embryos through a plethora of personalized meanings and emotions, intergenerational obligations as well as religious and folk beliefs. The ultimate outcomes of the tensions that have evolved in these three areas are at present not clear, but with further developments in human germ line gene editing, additional changes and conflicts regarding definitions of the embryo's legal and moral status can be expected.

An unresolved question is, whether the divergent and conflicting definitions of the embryo's legal status (in the three legal domains that we have described) have themselves been a factor that accounts for the fact that Chinese researchers have adopted human embryo gene editing research more than a year before researchers in other countries. This question is extremely difficult to answer. While it is true that the one-child policy has for more than three decades devalued unborn human life, it is also true that claims that the value of human embryos and reproductive tissues foetuses in China is generally regarded low (as a result of the policy) cannot be maintained. As mentioned by Nie, the Chinese birth politics may have facilitated access to aborted embryonic and foetal tissue for research and therapeutic purposes (Nie 2005), but with the advent of hESC the donation and use of human embryos has become subject to various safeguards that involve informed consent, IRB review and the prohibition to commodify human reproductive tissues. Nevertheless, the normalization of pregnancy termination and the existence of a more secular and utilitarian view of in-vitro fertilized embryos and aborted embryos, at least among many scientists, clinicians and in formal political discourse, may well have supported the rapid move ahead in human embryo gene editing. In order to arrive at a more consistent answer to this question, further research will be required that examines the perceptions, considerations and actions of scientists who operate in this field. Research will be required, in particular, into interactions and possible conflicts between scientists and the legal system, processes of embryo and gamete donation as well as regulatory approval practices for human embryo gene editing research.

We end this article with three lines of considerations that might structure future studies on this issue. First, scientists are usually well aware of the kinds of

incentives that compliance with legal rules creates. If scientists can choose from multiple legal or regulatory options, or they can exploit regulatory loopholes without serious sanctions, they may make use of these possibilities and sometimes completely avoid compliance with regulatory guidelines or the law (Raz 1972). At a more general level, law should strive to provide certainty and balance reliability against flexibility, in order to facilitate consistent and predictable applications. The uncertainties and multiple definitions of the legal status of human embryos in China's legal system, it seems to us, facilitate the selection of different kinds of legal definitions, and in particular those on whose basis the use and genetic modification is easily justified. By being able to treat and procure human embryos as disposable biological entities, whose use in research has potentially wide-ranging social benefits, approval for research in the context of local IRBs may be easier than in other countries in whose legal system the human embryo has been ascribed the status of a "human being".

While it is true, as Zhai, Ng and Lie (2016) have pointed out, that current regulatory guidelines for human germ line gene editing are comparable to regulatory instruments in other countries, these rules do not yet adequately address the potential social implications of this research and the legal and moral dilemmas that are likely to result from it. It is important to point out in this regard, that the legal and regulatory tools that guide human germ line research in China today take a relatively narrow ethical view on this emerging research field. Principles such as informed consent, autonomy and ethical review focus in most respects on the protection of scientists and the donors of human embryos. This rather "narrow" regulatory approach seems to ignore the broader societal implications of human embryo gene editing research, including the challenges to systematically govern this technology field across China's large territory and thousands of medical institutions.

A second line of consideration is the strong financial stakes that underlie gene-editing research, including human germ line gene-editing research. Considering the widespread investments that can currently be observed in this research field, the issuing of clear and robust regulation seems crucial. This must also involve a consistent conception of the legal status of human gametes and embryos in China and other countries. An important question in this respect is whether the prospect of new investments and, some way down the line, the generation of financial profits may actually disincentivise the adoption, implementation and use of coherent regulatory and legal frameworks in this research field. As the case of clinical stem cell research has shown, legal and regulatory uncertainties can be an important factor in attracting investments. Investors may read the existence of lenient or minimal regulation as a sign that scientists and governments prioritize rapid technology developments and corresponding applications above the implementation of consistent and more stringent regulatory rules, which may increase research expenses and delay possible forms of applications. In other words, the nature of research competition in the CRISPR field may generate a dynamic that may loosen the tenets of cautious rationalism and give rise to premature and not systematically thought through real-world applications, with potentially harmful effects. The uncertain and contested legal status of human embryos in China is likely to add fuel to the fire of this "gene editing rush" and to expedite the booming of CRISPR human applications.

A final line of consideration is that the cost of legal uncertainty may decrease public involvement in the design and implementation of public policy. The uncertain and contested legal status of the human embryo can render the public confused. This may result in ambiguities about the exact definitions that are handled in different regulatory domains, which in turn makes is more difficult to address the problems

caused by biotechnology progress such as hESC research and CRISPR gene editing. Public awareness and confusion regarding the regulation of medical technologies have in recent years been highlighted by broadening mass media coverage of medical and legal controversies. In the light of these reports, many scientists and policy makers fear that the engagement of the public may hinder research progress. Often heard reasons, as exemplified by the case of hESC research, are that citizens are likely to be insufficiently informed or to misunderstand the purposes of science, and alternatively that their concerns may slow down the research process as well as the articulation and issuing of policies and regulatory frameworks. These arguments should not be taken for granted and further research into the public perceptions of embryo research in China and globally is recommended.

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References:

Adams, V., Erwin, K. and Le, P. (2010) Governing Through Blood Biology, Donation, and Exchange in Urban China, in Ong, A. and Chen, N. N. ed., Asian Biotech: Ethics and Communities of Fate 167-190.

Beijing Times. (2015) More than 70% of 10,000 embryos left from IVF were discarded by their parents. (In Chinese). 27 September: p8.

Biological Discovery Network. (2015) National Natural Science Foundation of China in 2015: 57 CRISPR Projects grasp gold. (In Chinese). http://mt.sohu.com/20150824/n419588626.shtml, accessed 21 January 2017.

Bosley, K.S., Botchan, M., Bredenoord, A.L., Carroll, D., Charo, R.A., Charpentier, E., Cohen, R., Corn, J., Doudna, J., Feng, G. and Greely, H.T. (2015) CRISPR germline engineering—the community speaks. Nature 33(5): 478-486.

Bound, K., Saunders, T., Wilsdon, J. and Adams, J. (2013) China's absorptive state: Research, innovation and the prospects for China-UK collaboration. Online book. http://sro.sussex.ac.uk/47851/1/chinas_absorptive_state.pdf, accessed 21 January 2017.

Callaway, E. (2016) Gene-editing research in human embryos gains momentum. Nature 532(7599): 289-290.

Cheng, L., Qiu, R.Z., Deng, H., Zhang, Y.A., Jin, Y. and Li, L. (2006) Ethics: China already has clear stem-cell guidelines. Nature 440(7087): 992-992.

Commission of Legislative Affairs (CLA). (2010) The Development and Morality of Human Embryonic Stem Cell, The State Intellectual Property Office of P.R.C,

http://www.sipo.gov.cn/mtjj/2006/200804/t20080401_362185.html,accessed online 21 January 2017.

Cookson, C. (2005) Country report: China. Financial Times,17 June: 1.

Cong, Y. (2008) From Chinese Values of Life to Exploring the Ethical Aspects of Stem Cell Research in Mainland China. Contemporary Chinese Thought 39(2): 18-31.

Craswell, R. and J.E. Calfee (1986) Deterrence and Uncertain Legal Standards. Journal of Law, Economics and Organization 2(2):279-303.

Cyranoski, D. (2015) What China's latest five-year plan means for science. Nature 531(7595):424-424.

Greenhalgh, S. and E.A. Winckler (2005). Governing China's population: from Leninist to neoliberal biopolitics. Stanford, CA: Stanford University Press.

He, X. (2016) Report of the National Bureau of Statistics: the national education level of the population increased significantly. (In Chinese). 20 April, http://money.163.com/16/0420/15/BL3THR3K00253B0H.html, accessed 21 January 2017.

Hu, C.L. (2009) Comments on the best practice in ethical governance of biological and biomedical research collaboration between Chinese and European Scientists. Speech to Final Conference - Ethical Governance of Biological and Biomedical Research: Chinese-European Co-operation. London, 3 September.

Jasanoff, S. (2005) Designs on Nature: Science and Democracy in Europe and the United States, Princeton University Press

Jiang, L. (2016) Regulating Human Embryonic Stem Cell in China- A Comparative Study on Human Embryonic Stem Cell's Patentability and Morality in US and EU, German: Springer.

Jin, X., G. Wang, S. Liu, M. Liu, J. Zhang, and Y. Shi. (2013) Patients' Attitudes towards the Surplus Frozen Embryos in China. BioMed Research International 2013(7): 1-8.

Kang, X., He, W., Huang, Y., Yu, Q., Chen, Y., Gao, X., Sun, X. and Fan, Y. (2016) Introducing precise genetic modifications into human 3PN embryos by CRISPR/Cas-mediated genome editing. Journal of assisted reproduction and genetics 33(5): 581-588.

LaBarbera A.R. (2016) Proceedings of the International Summit on Human Gene Editing: a global discussion—Washington, DC, December 1–3, 2015. Journal of Assisted Reproduction and Genetics 33(9): 1123-1127.

Lanphier, E., Umov, F., Haecker, S.E., Werner, M. and Smolenski J. (2015) Don't edit the human germ line. Nature 519(7544): 410-411.

Ledford, H. (2015) CRISPR, the disruptor. Nature 522(7554): 20-24.

Long, W. (2012) Illegal abortion: the crime of abortion in Republic of China and its practice. (In Chinese). Modern Chinese History Studies 1: 92-104.

Mann, C.C. (2003) The first cloning superpower. Wired Com, 11 January, http://www.wired.com/wired/archive/11.01/cloning_pr.html, accessed 20 January 2017.

Mans, R., Rossum, H.M., Wijsman, M., Backx, A., Kuijpers, N.G., van den Broek, M., Daran-Lapujade, P., Pronk, J.T., van Maris, A.J. and Daran, J.M.G. (2015) CRISPR/Cas9: a molecular Swiss army knife for simultaneous introduction of multiple genetic modifications in Saccharomyces cerevisiae. FEMS yeast research 15(2):fov004.

Matthews, K.R. and M.L. Cuchiara (2014) Gene patents, patenting life and the impact of court rulings on US stem cell patents and research. Regenerative Medicine 9(2): 191-200.

Mitzkat, A., Haimes, E. and C. Rehmann-Sutter (2010) How reproductive and regenerative medicine meet in a Chinese fertility clinic. Interviews with women about the donation of embryos to stem cell research. Journal of Medical Ethics 36(12): 754-757.

Nie, J. B. (2005) Behind the silence: Chinese voices on abortion. Lanham, MD: Rowman & Littlefield Publishers.

Ong, A. (2010) An Analytics of Ethics and Biotechnology at Multiple Scales, in Ong, A. and Chen, N. N. ed., Asian Biotech: Ethics and Communities of Fate 1-55

Pan, L.T. (2006) The 1st Five-Year Plan (1953-1957). 5 April, http://www.gov.cn/english/2006-04/05/content_245703.htm, accessed 21 January 2017.

Qiu, R.Z. (2004) Bioethics: Asian Perspectives – A Quest for Moral Diversity. Dordrecht and Boston: Kluwer Academic Publishers.

Qiu, R.Z. (2007) The historical, social and philosophical background of Chinese policies regarding human embryonic stem cell research. Paper presented at the BIONET workshop on Bio-ethical Governance of Stem Cell Research; 10 October 2007 Shanghai, China.

Raz, J. (1972) Legal principle and the limits of law. Yale Law Journal 81(5): 823-842.

Rosemann, A. and H.Y. Luo (under review) Attitudes on the Donation of Human Embryos for Stem Cell Research among Chinese IVF Patients and Students, Journal of Bioethical Inquiry.

Rosemann, A., Jiang, L. and X.Q. Zhang (accepted). The Regulatory and Legal Situation of Human Embryo, Gamete and Germ Line Gene Editing Research and

Clinical Applications in the People's Republic of China. Commissioned Background Paper. Nuffield Council of Bioethics.

Savulescu, J., Pugh, J., Douglas, T. and Gyngell, C. (2015) The moral imperative to continue gene editing research on human embryos. Protein & cell 6(7): 476-479.

Servick, K. (2017) First U.S. team to gene edit human embryos revealed. Science (July 27, 2017), doi:10.1126/science.aan7170

Shi, Y.C., Zhang, S.B., and X.L. Zhuang (2014) Parents Have the Right to Monitor and Dispose the Inherited Frozen Embryo. (In Chinese). People's Judicaure Application 22: 32-36.

Sleeboom-Faulkner, M. (2014) Global morality and life science practices in Asia: assemblages of life. London: Palgrave MacMillan.

Sleeboom-Faulkner, M. (2010) Boundary Making and 'Good' Stem Cell Research (SCR) in Mainland China: Including Bioethics, Excluding Debate. East Asian Science, Technology and Society 4(1): 31-51.

Song G.B. (1933) Medicine Ethics. (In Chinese). Beijing: Guoguang press.

Standing Committee. (2008) Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China) http://www.wipo.int/wipolex/en/text.jsp?file_id=178664, accessed 21January 2017.

State Intellectual Property Office (SIPO). (2010) Guidelines on the Examination of Patents (promulgated by Order No. 55 of the State Intellectual Property Office (SIPO). http://www.wipo.int/wipolex/en/details.jsp%20?id=6511, accessed 21 January 2017.

State Intellectual Property Office (SIPO). (2013) The 5972 re-examination decision by the patent review committee. (In Chinese). http://app.sipo-reexam.gov.cn/reexam-out/searchdoc/decidedetail.jsp?jdh=FS5972&lx-fs, accessed 21 January 2017.

Stein, R. (2016) Breaking Taboo, Swedish Scientist Seeks To Edit DNA Of Healthy Human Embryos. SHOTS Health News, 22 September, http://www.npr.org/sections/health-shots/2016/09/22/494591738/breaking-taboo-swedish-scientist-seeks-to-edit-dna-of-healthy-human-embryos, accessed 21 January2017.

Sterckx, S. (2008) The WARF/Stem cells case before the EPO Enlarged Board of Appeal. European Intellectual Property Review 30(12): 535-537.

Sun, L.G. (2015) The Legal resolution of frozen human embryo between the couple. (In Chinese) Journal of National Prosecutors College 23(1): 110-120

Tatlow, D. (2015) A scientific ethical divide between China and the West. New York Times, 30 June, http://www.nytimes.com/2015/06/30/science/a-scientific-ethical-divide-between-china-and-west.html, accessed 5 September 2016.

Thompson, C. (2010) Asian Regeneration? Nationalism and Internationalism in Stem Cell Research in South Korea and Singapore, in Ong, A. and Chen, N. N. ed., Asian Biotech: Ethics and Communities of Fate 95-118.

Tu, L. (2008) Exploration on ethical governance of donated oocytes and embryos for ES cell research. Paper presented at the BIONET Conference on ethical governance of reproductive technologies, therapeutic stem cells and stem cell banks: April 2008; Changsha, PRC.

Vincent, J. (2015) Scientists in China edit human genome in embryos for the first time. The Verge, 23 April, http://www.theverge.com/2015/4/23/8477491/human-genome-editing-embryo-china-crispr , accessed 5 September 2016.

Vlassoff, C. and Shah, I. (1990) The Infertility Revolution in China. IDRC Reports 18(4): 16-17.

Wahlberg, A. (2016) The birth and routinization of IVF in China. Reproductive Biomedicine & Society Online 2: 97-107.

Wang, Y. G. (2003) Chinese Ethical Views on Embryo Stem Cell Research. In: S.Y. Song, Y.M. Koo, and D. Macer (eds.). Asian Bioethics in the 21st Century. Eubios Ethics Institute. Online Book (chapter 3) http://www.eubios.info/ABC4/abc4049.htm, accessed 21 January 2017.

Wang, Y.W. (2006) Estimation on the effects of China's Birth Control Policy Chinese. (In Chinese). Journal of Population Science 5: 23-32

Wu, Z.M. (2013) The 5972 Re-examination Decision by the Patent Review Committee-the Preparation of Pre-implantation Embryos for Therapeutic Cloning Use. (In Chinese). http://www.bioipr.com/biopharma-ipr/1108/, accessed 21 January 2017.

Yang, N. (2015) JinJia and Zhongshan University signed a technology development cooperation contract. (In Chinese). http://www.cs.com.cn/ssgs/gsxw/201512/t20151230_4874293.html, accessed 21 January 2017.

Yang, L.X. (2014) The Legal Status of Frozen Human Embryo and its Inheritance. (In Chinese). People's Judicature 13: 25-30.

Yang L.X. (2015) The Conservatism and Innovation of the Judge. (In Chinese). The Legal Science Journal 5: 1-10.

Zhai, X.M., Ng, V. and R.D, Lie. (2016) No ethical divide between China and the West in human embryo research. Developing World Bioethics 16(2): 116-120.

Zhang, Y. (2006) A Study of the Historical Development of China's Population Control and its Trend. (In Chinese). Journal of Guangzhou University (Social Science Edition) 5: 15-22.

Zhang, X., (2015) Urgency to Rein in the Gene-editing Technology. Protein & cell *6*(5): 313-313.

Zhang, S.B., Fan L. and X.L. Zhuang. (2014) The Analysis of Disposal and Monitoring of Frozen Embryo. (In Chinese). Journal of Law Application 11: 41-47.

Zhang, Q. and Sun, J. (2013) The Legal Analysis of forced abortion case. (In Chinese). Journal of Nanjing College for Population Programme Management 29(3): 71-75.

Zhou X. (2012) The Right to Life of Human Foetus and Its Criminal Protection. (In Chinese). Law Science Journal 8:51-60.